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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-------------------------|------------------|
| 10/669,099 | 09/22/2003 | Stephen R. Gorfine | 010692-004532US | 1846 |
| 20350 | 7590 | 06/17/2005 | EXAMINER | |
| TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834 | | | TATE, CHRISTOPHER ROBIN | |
| | | ART UNIT | PAPER NUMBER | |
| | | 1654 | | |

DATE MAILED: 06/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|---------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/669,099 | GORFINE, STEPHEN R. |
| | Examiner | Art Unit |
| | Christopher R. Tate | 1654 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 11 April 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 37-39, 41-57 and 60-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 7-39, 41-57 and 60-65 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

The amendment filed 11 April 2005 is acknowledged and has been entered. Claims 37-39, 41-57, and 60-65 have been examined on the merits. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Double Patenting

Claims 37-39, 41-57, and 60-65 (as amended) stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21-26 of U.S. Patent No. 5,504,117 and over claims 7-20 of U.S. Patent No. 5,693,676 for the reasons set forth in the previous Office action (with respect to the instantly claimed method of ameliorating pain in a human associated with the selected anal disorders recited in the amended claims - as discussed below).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed method and the claimed methods of US '117 and US '676 are each drawn to a method of ameliorating (controlling) pain associated with an anal disease/disorder - e.g., an anal fissure, anal ulcer, hemorrhoidal disease, and/or levator spasm via administering a composition comprising an effective amount of a nitric oxide donor (such as nitroglycerin or L-arginine) to the affected anal area/anal canal of a subject in need thereof. In addition, it would clearly have been obvious to one of ordinary skill in the art at the time the claimed invention was made to further include an art-recognized pain-relief agent such as a corticosteroid and/or local anesthetic within such a topical therapeutic composition for the well known benefits such an agent provides in terms of aiding in effectively providing pain relief to such a subject. Further, the instant claims encompass or are encompassed by the claimed methods of US '117 and '676.

Applicants' response to the above obviousness-type double patenting rejections is that they be held in abeyance until some claims are deemed to be in condition for allowance at which time they intend to submit a suitable terminal disclaimer obviating these rejections. Accordingly, the ODP rejections stand until a suitable terminal disclaimer has actually been submitted.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1654

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Christopher R. Tate
Primary Examiner
Art Unit 1654